



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,637	10/24/2003	Richard P. Gill	L0532.70034US00	2608

7590 06/14/2007  
Alan W. Steele, M.D., Ph.D.  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
----------

GAKH, YELENA G

ART UNIT	PAPER NUMBER
----------	--------------

1743

MAIL DATE	DELIVERY MODE
-----------	---------------

06/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/694,637

Applicant(s)

GILL ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-13, 20, 36, 39-42, 49, 65, 68-71 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 14-19, 21-35, 37, 38, 43-48, 50-64, 66, 67, 72-77 and 79-92 is/are rejected.
- 7) ☒ Claim(s) 6, 35, 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 03/30/05, 12/27/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to the following patentably distinct species: precipitating agent comprises: a cationic or quaternary surfactant (claims 7, 36 and 65), a quaternary ammonium bromide, in particular MYTAB (claims 8-9, 37-38 and 66-67), quaternary ammonium chloride (claims 10, 39 and 68), quaternary acrylate salt and acrylamide (claims 11, 40, 69), a copolymer of sodium acrylate and acrylamide (claims 12, 41 and 70), a polyacrylamide and/or polyamine (claims 13, 42 and 71). The species are independent or distinct because these precipitation agents are different chemical compounds and require a separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1, 30 and 59, respectively, are generic.

This application contains claims directed to the following patentably distinct species: the tracer is detected directly (claims 19, 48 and 77), the tracer is detected indirectly (claims 20, 49 and 78). The species are independent or distinct because direct and indirect detection of the tracer requires different experimental set-up and requires a separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1, 30 and 59, respectively, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1743

2. During a telephone conversation with Neil P. Ferraro on 06/06/07 a provisional election was made without traverse to prosecute the invention related to MYTAB precipitation agent and to the direct detection of tracers, claims 8-9, 37-38, 66-67, and claims 19, 48, 77, respectively. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7, 10-13, 20, 36, 39-42, 49, 65, 68-71 and 78 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-6, 8-9, 14-19, 21-35, 37-38, 43-48, 50-64, 66-67, 72-77 and 79-92 are considered on merits.

### ***Double Patenting***

3. Applicant is advised that should claim 1 be found allowable, claim 88 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Objections***

4. Claims 6, 35 and 64 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of the claims should be inherent to the method recited in the parent claims in order to have enabled method, because if the tracer were precipitated along with the coloring agent, it would not be possible to detect it in the sample supernatant.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1743

6. Claims 1-5, 8-9, 14-19, 21-34, 37-63 and 65-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method in which the precipitation of the coloring agent does not cause the precipitation of the tracer, does not reasonably provide enablement for the method, in which the precipitation of the tracer takes place. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. If the tracer is precipitated along with the coloring agent, there is no way for any person of ordinary skill in the art to detect it in the sample supernatant, which is the major step of the claimed method.

Claims 8-9, 27-29, 37-38, 56, 58, 66-67, 85 and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method in which MYTAB precipitates negatively charged caramel coloring agent, does not reasonably provide enablement for the method, in which the MYTAB is applied to positively charged caramel coloring agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. MYTAB is a cationic surfactant, and therefore it is impossible to precipitate cationic caramel coloring agents with MYTAB.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6, 8-9, 14-19, 21-35, 37-38, 43-48, 50-64, 66-67, 72-77 and 79-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 30, 59 and 88 recite a method for detecting a tracer in a preparation comprising a coloring agent by first precipitating the coloring agent and then detecting the tracer in the supernatant. The purpose of the method is not clear, if the coloring agent is not interfering with detection of the tracer. The examiner considers the recitation of claims 2, 31 and 60 the critical element of the method and suggests incorporating it into the independent claims.

Several pending claims, e.g. claims 4-5, 33-34, 62-63, recite Type I, Type 2 and Type 3 caramel color. The specification describes these types of the caramel colors as the following: "in one embodiment wherein a Type 1 caramel color (also known as "acid-proof" or "beverage

Art Unit: 1743

type”) is employed in the preparation as the coloring agent, a Type 2 caramel color (also known as "brewer's color") or a Type 3 caramel color (also known as "baker's color") may be used as a precipitating agent. Type I has electronegative colloidal characteristics and will be precipitated by an agent having an electropositive character, such as Type 2 or Type 3. Correspondingly, if Type 2 or Type 3 is used as the coloring agent, Type 1 may act as a precipitating agent” (page 12). This classification of the caramel colors does not appear to be conventional in the art. For example, Royle et al. discloses in “Analysis of caramels by capillary electrophoresis and ultrafiltration”, (J. Sci. Food Agric., 1999): “the International Technical Caramel Association divides caramels into four different categories according to the reactants added to the sugar during caramelisation. Class I caramels are produced by heating sugar at high temperature without the addition of nitrogenous ‘catalysts’; they are used for coloring spirits such as whisky. Class II caramels have small amounts of sulphite added as reactant, and are used in aperitifs. Class III caramels have ammonia as reactant, producing highly coloured caramels which are widely used in beers and foodstuffs. Ammonium sulphites are used as reactants for production of Class IV caramels; these highly coloured, negatively charged caramels are used in cola type beverages”. The same classification is used in the article by Wade, “Caramel color-conscious”: caramel colors are classified into Classes I-IV: Class I (“plain”) caramels do not contain ammonium or sulfate compounds. Class II caramels process caustic sulfite; caramels of Class III are created by processing sugars with only ammonia. Caramels of Classes I, II and IV are also characterized as having negative colloidal charge, with only the caramels of Class III having positive charge.

Therefore, this classification is different from the one proved by the Applicants. The Applicants are respectfully requested to provide any reference, which teaches caramel classification disclosed by the Applicants with a more detailed description of the caramel types characteristics. Since the classification of the caramels provided by the Applicants in the specification is not universal and conventional, and the description of different caramel types is not complete, the examiner considers the definitions of the caramels as Type 1, Type 2 and Type 3 caramels recited in the claims unclear and indefinite. If the Applicants intended to emphasize that different types of caramels have opposite charges and therefore can be used as precipitation agents in the claimed method, the examiner suggests the Applicants to indicate this characteristic

Art Unit: 1743

of the caramels in the claims by reciting e.g. "electronegative Type 1 caramel color".

Claims 8-9, 37-38, 56-58 and 66-67 recite a quaternary ammonium bromide and MYTAB. It is not apparent from the claims the way they are written, if these are precipitation agents recited in the parent claim. If these are the precipitation agents, the examiner suggests the Applicants to amend the claims by reciting e.g. for claim 8: "the method of claim 1, wherein the precipitation agent is a quaternary ammonium bromide" and for claim 9: "the method of claim 8, wherein the quaternary ammonium bromide is ... MYTAB". This makes the language of the claims much simpler and clearer. The examiner suggests amending all other claims in the same way in order to create antecedent basis for all consecutive limitations.

From claims 21, 50, 57, 79 and 86 it is not clear, what is a food dye. Is the tracer is a food dye? If this is the case, it should be clearly recited in the claim: claim 21: "the method of claim 1, wherein the tracer is a food dye". If the food dye is something else, then it is not clear, as to what is its function in the method. The same is true for all other claims reciting the food dye. Also, for claims 22, 51 and 80 the examiner assumes that FD&C Blue #1 is the food dye. If this is correct, the claims should be amended as e.g.: claim 22: "the method of claim 21, wherein the food dye is FD&C Blue #1". Amendment should be made to all corresponding claims of other groups. Since from the pending claims it is not apparent, if the food dye is not the caramel color, which is present in the preparation, the examiner considers the food dye the caramel color.

The same problem exists for the limitation a "light-sensitive compound" in claims 23, 52 and 81. It is unclear as to what this "light sensitive compound" might be. Is it degrading upon irradiation with light? Is it optically detectable? Also, it is apparent, as to how this compound is related to the tracer, or to the coloring agent, or to the precipitation agent? The limitation the "light-sensitive compound" renders the claims unclear and indefinite, since it is not apparent, as what is the function of the light-sensitive compound" in the claimed method.

In general, the examiner suggests rewriting the pending claims in a simpler format, such as: claim 2: "the method of claim 1, wherein the coloring agent interferes with the tracer"; claim 3: "the method of claim 1 wherein the coloring agent is a caramel coloring agent", etc. It is not necessary to repeat all the steps from the parent claims, which makes dependent claims with higher numbers almost unreadable, and which results in indefinite language. Also, such language of the claims raises the issues with antecedent basis for limitations.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1-2, 6, 16-19, 23, 25-26, 88 and 90-92** are rejected under 35 U.S.C. 102(b) as anticipated by anyone of Parekh (US 3,615,232, IDS), Das (US 4,211,531), Wang et al. (US 4,734,378), or Meucci et al. (US 5,135,875).

Parekh discloses “method and reagent for determining total cholesterol in blood serum”. “In a method for the determination of total cholesterol in blood serum, plasma or other cell free body fluid the steps of adding a reagent comprising a mixture of ferric acetate [ $\text{Fe}(\text{C}_2\text{H}_3\text{O}_2)_3$ ] and uranium acetate [ $\text{UO}_2(\text{C}_2\text{H}_3\text{O}_2)_3$ ] to the fluid whereby the total cholesterol content thereof is solubilized and *those chromogens which interfere with the determination are precipitated and separating the liquid phase containing solubilized cholesterol from the precipitate*. The cholesterol content is then determined quantitatively, preferably colorimetrically, employing as a color-developing reagent a mixture of ferrous sulfate and sulfuric acid” (Abstract). The precipitation of proteins with protein precipitating agents is usually complete, with the protein concentration in the supernatant close to zero. Cholesterol can be considered a trace material as the component of blood. Blood contains light-sensitive compounds, such as hemoglobin. Calibration of optical detection using reference spectra is a conventional procedure.

Das teaches a similar method for colorimetric cholesterol assay comprising precipitation interfering proteins, such as hemoglobin, and detecting cholesterol (a trace component) in the blood sample directly by colorimetric measurement using calibration reference samples (see Abstract).

Wang teaches “precipitation of interfering proteins in fluorescence polarization immunoassay for dioxine”, which comprise all the steps recited in the indicated claims (see Abstract).

Meucci teaches a similar method of detecting trace proteins by precipitating interfering coloring proteins such as hemoglobin and directly measuring the trace component directly by fluorescent polarization technique using calibration reference samples (see Abstract).



Art Unit: 1743

***Claim Rejections - 35 USC §103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. **Claims 3-4, 14-15, 21, 24, 30-33, 35, 43-48, 50, 52-55, 57, 59-62, 64, 72-77, 79, 81-84, 86 and 89** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Parekh, Das, Wang or Meucci in view of Selinfreund (US 6,458,595).

While Parekh, Das, Wang or Meucci teaches a method of removing interfering coloring agents from biological samples for a direct colorimetric detection of biological constituents (tracers) in the sample, they do not specifically teach such method for detecting tracers in e.g. colored beverages or other food items.

Selinfreund teaches "automated fingerprint methods and chemistry for product authentication and monitoring", with the methods comprising adding optically detectable tracers such as dyes and determining authenticity of the products, including coca-cola.

It would have been obvious for any person of ordinary skill in the art to expand the application of Parekh/Das/Wang /Meucci's method to detecting tracers in colored food including beverages, such as coca-cola, as taught by Selinfreund, because optically detectable tracers can be hindered by the food color, such as conventional caramel color used for beverages, including coca-cola, and therefore the interfering coloring agents should be precipitated the way taught by Parekh, Das, Wang or Meucci. Authentication of the product inherently comprises comparing a test sample with a reference sample prepared in the same way. It would have been obvious for any person of ordinary skill in the art to first prepare a liquid sample from a non-liquid sample before adding a detectable tracer (claim 89).

15. **Claims 5, 34 and 63** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Parekh, Das, Wang or Meucci in view of Selinfreund (US 6,458,595), as applied to claims 3-4, 14-15, 21, 24, 30-33, 35, 43, 45-48, 50, 52-53, 59-62, 72, 74-77, 79, 82-84, 89-92 above, and further in view of Kamuf ("Caramel Color", IDS) or Kuntz ("Natural Food Colors", IDS).

Parekh, Das, Wang or Meucci in view of Selinfreund do not specifically disclose positively and negatively charged caramel colors Types 1, 2 and 3), which can be precipitated by the oppositely charged caramel colors in order to detect other colored traces.

Kamuf and Kuntz disclose different classes of caramel colors, including positively and negatively charged caramel colors, which precipitate upon adding caramel colors of the opposite charge (Kamuf, page 3, the last paragraph; Kuntz, page 2). It would have been obvious for any person of ordinary skill in the art to apply Parekh's method specifically to beverages containing caramel colors along with other coloring agents, with caramel colors interfering with detecting other coloring agents, because Kamuf and Kuntz indicated that one type of caramel colors can be precipitated by an oppositely charged type of caramel colors thus avoiding well-recognized problem of interfering caramel colors with detecting other colored agents (traces).

16. **Claims 22, 51 and 80** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Parekh, Das, Wang or Meucci in view of Selinfreund, as applied to claims 3-4, 14-15, 21, 24, 30-33, 35, 43, 45-48, 50, 52-53, 59-62, 72, 74-77, 79, 82-84, 89-92 above, and further in view of e.g. Perillo (SSSAJ, 1998).

While Parekh, Das, Wang or Meucci in view of Selinfreund do not specifically disclose FD&C Blue #1 tracer, Perillo teaches using food dye FD&C Blue #1 as a tracer for water and

Art Unit: 1743

solute flow in soil because of its high sensitivity for optical detection.

It would have been obvious for any person of ordinary skill in the art to use FD&C Blue #1 as a tracer in a preparation and apply Parekh, Das, Wang or Meucci in view of Selinfreund's method for its detection, because Perillo teaches its high sensitivity as a tracer.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/7/07



**YELENA GAKH  
PRIMARY EXAMINER**